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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,570

07/11/2003

Seppo Yla-Herttuala

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08/08/2006

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,570	YLA-HERTTUALA ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-37 is/are pending in the application.
- 4a) Of the above claim(s) 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22, 25, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 23, 24 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> . |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed on 06/05/2006 has been entered in full. Claims 1-17 have been canceled. Claims 18-37 have been added. Claims 18-37 are pending. Claims 18-28 are under consideration. Claims 29-37, which are drawn to a medicament for therapeutic use comprising a nucleic acid molecule or a vector, have been withdrawn from consideration because the invention of claims 29-37 is directed to gene therapy and is distinct from the elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

All the rejections and objections set forth in the previous office action have been made moot by canceled claims.

Claim Rejections Under 35 USC § 102 (b)

Claims 18-21, 25, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantor et al. (WO 87/05026, August 27, 1987).

Cantor et al. teach a fusion protein comprising streptavidin and human LDL receptor (see Example 2): streptavidin at the N-terminal region and the LDL receptor at the C-

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terminal region of the fusion protein (first paragraph of page 28). The region of the LDL receptor gene used in the fusion is the region that encodes for 159 amino acids of the C-terminal region of the protein. In the native receptor this region comprises a short extracellular tail (88 amino acids), the membrane-spanning region (22 amino acids), and the intracellular domain (49 amino acids) (the 2nd paragraph of page 28). Cantor et al. also a nucleic acid molecule encoding the fusion protein, a recombinant expression vector, including bacterial or viral origin (lines 25-30 of page 9), and a process for production of the fusion protein (Example 2 and claims 25, 31, 32, and 45). Thus, the teachings of Cantor et al. meet the limitations of claims 18-21, 25, 27, and 28.

Applicants argue that there is no teaching or suggestion of any therapeutical benefit or application for the expressed fusion protein. This is not found to be persuasive because the instantly disclosed use for the product does not limit the scope of the invention, since the cited prior art teaches the same product, the rejection of the claims under 35 U.S.C. 102(b) is required.

Claim Rejections Under 35 USC § 103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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(ii). Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (WO 87/05026, August 27, 1987) as applied to claims 18-21, 25, 27, and 28 above, and further in view of Krieger et al. (U.S. Patent No. 5,510,466, April 23, 1996).

Cantor et al. teach a nucleic acid encoding a fusion protein comprising streptavidin and human LDL receptor as applied to claims 18-21, 25, 27, and 28 above.

Cantor et al. fail to teach a nucleic acid encoding a fusion protein comprising streptavidin and a scavenger receptor class A.

Krieger et al. teach a nucleic acid (Fig. 3) encoding a scavenger receptor class A (see attached sequence alignment).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make a nucleic acid encoding a fusion protein comprising streptavidin and a scavenger receptor class A taught by Krieger et al. with a reasonable expectation of success. One would have been motivated to do so because such a nucleic acid encoding the fused protein is capable of expressing the fused protein in vivo and the fused protein comprising streptavidin may be used to detect and purify a target protein of interest as taught by Cantor et al. (the middle of page 4).

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Claim Objections

Claims 23, 24, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
August 6, 2006

RUIXIANG LI, PH.D.
PRIMARY EXAMINER